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SUMMARY

Device Name: **TERUMO® 31G ThinPro™ Insulin Syringe**

Classification Name: **Piston syringe with fixed hypodermic single lumen needle**

INTENDED USE

The TERUMO® 31G ThinPro™ Insulin Syringe, with fixed hypodermic single lumen needle, is a device intended for medical purposes for the manual aspiration of fluids, and for the injection of fluids into parts of the body below the surface of the skin. This device is intended particularly for the aspiration and injection of insulin. This syringe with 31G needle is indicated for general use and for pediatric patients. The pediatric indication is cleared for the Terumo 30G Insulin Syringe (K001474 - Pediatric Indication).

DESCRIPTION

The TERUMO® 31G ThinPro™ Insulin Syringe is a sterile, single use piston syringe with a fixed hypodermic single lumen needle, designed for manual use. The syringe is available in 3/10 cc, ½ cc, and 1 cc volumes with a 31 gauge by 3/8 inch fixed hypodermic single lumen needle. Each syringe includes unit markings (3/10 cc = ½ unit markings, ½ cc = single unit markings, and 1 cc = two unit markings).

SUBSTANTIAL EQUIVALENCE

The TERUMO® 31G ThinPro™ Insulin Syringe submitted in this 510k is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared TERUMO® Insulin Syringe (K822083, K992802, & K001474 – Pediatric Indication) and the Becton Dickinson® Ultra-Fine™ II Insulin Syringe (K955235).

PRINCIPLE OF OPERATION/TECHNOLOGY

This device is operated manually.

MATERIALS

The materials used in this device are the same as used in the TERUMO® Insulin Syringe (K822083, K992802, & K001474 – Pediatric Indication).

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PERFORMANCE

The performance of this device is equivalent to the predicates.

CONCLUSION

The TERUMO® 31G ThinPro™ Insulin Syringe submitted in this Premarket notification is substantially equivalent to the TERUMO ® Insulin Syringe (K822083, K992802, & K001474 – Pediatric Indication) and Becton Dickinson® Ultra-Fine™ II Insulin Syringe (K955235) with respect to intended use, design, technology/principles of operation, and performance. Differences between the devices do not raise any new issues of safety or effectiveness.

Date Prepared: 6/12/2007

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Eileen Dorsey
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Elkton, Maryland 21921

JUL 11 2007

Re: K071630
Trade/Device Name: TERUMO® 31G ThinPro Insulin Syringe
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: June 12, 2007
Received: June 14, 2007

Dear Ms. Dorsey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K07 1630

Device Name: TERUMO® 31G ThinPro Insulin Syringe

Indications For Use:

The TERUMO® 31G ThinPro Insulin Syringe, with fixed hypodermic single lumen needle, is a device intended for medical purposes for the manual aspiration of fluids, and for the injection of fluids into parts of the body below the surface of the skin. This device is intended particularly for the aspiration and injection of insulin. This syringe with 31G needle is indicated for general use and for pediatric patients.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

7/4/07
for Chiu Lin PLD.
(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K071630